

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 18 JUL 2005

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|--|--|--|---------------------|
| Applicant's or agent's file reference<br>1199WOORD01   | <b>FOR FURTHER ACTION</b>                                |  | See Form PCT/PEA416 |
| International application No.<br>PCT/EP2004/051067   | International filing date (day/month/year)<br>09.06.2004 | Priority date (day/month/year)<br>13.06.2003                           |                     |
| International Patent Classification (IPC) or national classification and IPC<br>A61K31/58, A61K31/167, A61K9/12  |  |  |                     |
| Applicant<br>ALTANA PHARMA AG  |  |  |                     |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |  |  |                     |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>   |  |  |                     |
| Date of submission of the demand<br><br>10.12.2004   |  | Date of completion of this report<br><br>15.07.2005                    |                     |
| Name and mailing address of the International preliminary examining authority:<br> European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465  |  | Authorized Officer<br><br>Herrera, S<br><br>Telephone No. +49 89 2399- |                     |



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/051067

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-11 as originally filed

**Claims, Numbers**

1-11 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/051067

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

|                               |             |      |
|-------------------------------|-------------|------|
| Novelty (N)                   | Yes: Claims | 1-11 |
|                               | No: Claims  |      |
| Inventive step (IS)           | Yes: Claims |      |
|                               | No: Claims  | 1-11 |
| Industrial applicability (IA) | Yes: Claims | 1-11 |
|                               | No: Claims  |      |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Section V**

1. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: DE 195 41 689 A (BYK GULDEN LOMBERG CHEM FAB) 15 May 1996  
(1996-05-15)

D2: WO 97 47286 A (JINKS PHILIP A ;OLIVER MARTIN J (GB); PALING  
SIMON G (GB); JAISWAL) 18 December 1997 (1997-12-18)

D3: WO 93 11747 A (MINNESOTA MINING & MFG) 24 June 1993 (1993-06-24)

D4: WO 98 52542 A (MULLER HELGERT ;FATANIA KANU M (GB); OLIVER  
MARTIN J (GB); SCOTT J) 26 November 1998 (1998-11-26)

2. The subject-matter of the present claims is to be considered as novel in that none of the documents cited above disclose a combination of ciclesonide and formoterol together with HFA134a or HFA 227 or mixtures thereof.

3. It is however known to use formoterol and ciclesonide together from D1. The problem to be solved was therefore to find an improved galenic formulation for said combination. Since it is however well known from D2 to D3 to formulate both ciclesonide as well as formoterol in either HFA134a or HFA 227 or mixtures thereof, with or without a surfactant and with small amounts of ethanol (cf. parts indicated in the search report), it cannot be considered inventive to arrive at the subject-matter of the present claims. The requirements of Article 33 (3) PCT have therefore not been fulfilled.